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<p>(21) International Application Number: PCT/DK89/00215</p> <p>(22) International Filing Date: 15 September 1989 (15.09.89)</p> <p>(30) Priority data: 5156/88 16 September 1988 (16.09.88) DK</p> <p>(71)(72) Applicant and Inventor: NØRGÅRD, Tina, Møller [DK/DK]; Ælversensvej 16, DK-9800 Hjørring (DK).</p> <p>(74) Agent: HOFMAN-BANG & BOUTARD A/S; Adelgade 15, DK-1304 Copenhagen K (DK).</p> <p>(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), DK, FI, FR (European patent), GB (European patent), IT (European patent), LU (European patent), NL (European patent), NO, SE (European patent).</p>		<p>Published <i>With international search report. In English translation (filed in Danish).</i></p>	

Disposable liquid withdrawal equipment comprising a holder (10) adapted to receive collection tubes and consisting of a transverse member (11) with a firmly mounted double needle (121, 122) and one or more axial parts (131, 132, 133) connected with said needle, and a shield which movably surrounds the holder and is provided with a first cam means (21) for cooperation with a movable protective member (133), which covers the rear end (122) of the double needle in the final position of the equipment. The equipment moreover comprises a grip (132B), provided or arranged on one of the axial parts of the holder, to cooperate with a second cam means (22), provided or arranged on the inner side of the shield, to lock the holder in a position of use during blood withdrawal, and to cooperate with a slot (25), provided in the shield, with catches (24) to lock the holder in a permanent final position after completed blood withdrawal. The equipment is operated easily and simply by movement with the thumb and leaves the points of the double needle surrounded by the tube without any risk of accidental contact.

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Liquid withdrawal equipment

5 The invention concerns disposable liquid withdrawal equipment, preferably for taking samples of e.g. body fluids, such as blood and lymph, or other body fluids, comprising a holder adapted to repeatedly receive collection tubes and having a firmly mounted double needle and protective means and a shield, which movably surrounds the holder and
10 protects against accidental touch of the points of the double needle in cooperation with the protective means in its final position after completed withdrawal.

15 Liquid withdrawal equipment is widely used primarily at hospitals mainly for taking blood samples. According to known so-called "closed blood withdrawal systems" blood samples are taken directly from the vein through a double needle to an evacuated collection tube, without the blood getting in contact with the surrounding environment at any
20 time during withdrawal. After blood withdrawal with such an equipment, disassembly and disposal of it involves a great risk of accidental needle sticks. For diseases such as AIDS and hepatitis sticks from such used needles involve a risk of life-threatening infections. By correct
25 and careful use of known closed liquid withdrawal equipment it is possible to reduce the risk of such accidental infections. However, liquid sampling often takes place in situations of stress, timewise and otherwise, in which correct and careful security measures are cumbersome and
30 time-consuming and are therefore often ignored in practice.

Liquid withdrawal equipment with protection of the needle point against accidental touch before and after use is
35 known from e.g. the US Patent Specification No. 4 752 290. According to this prior art, a tubular protective shield

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surrounds a needle holder with a double needle and device for receiving collection tubes in such a manner that the shield, whose interior surface is formed at one end with raked teeth for engagement with the retaining ring on the exterior of the needle holder, can be moved axially and be retained in three positions. In the initial position, the needle is protected so that the needle points are present inside the shield whose front end is additionally closed by a protective cap. Upon removal of the protective cap the front point of the double needle is exposed so that it can be touched.

When the shield is axially displaced to the position of use, the shield is retained by a retaining ring, and a flange ensures that the shield cannot be pulled clear of the needle holder. After completed withdrawal the shield can be moved back and further on to the final position, from which the shield cannot again be moved back to its initial position. Corresponding to the initial position, the front point of the double needle can again be contacted in the final position.

According to this prior art, the degree of protection against accidental touch of the needle point depends upon the length and diameter of the shield, both of which being determined by the collection tube used.

To obtain a sufficiently safe effect, the shield must therefore be relatively long corresponding to a given collection tube, which makes handling unpractical, or for a shield of a given length the collection tube must have a relatively small diameter. E.g., a 10 ml collection tube with an internal diameter of 1.5 cm and a length of 7.5 cm demands a protective shield with an internal diameter of about 2 cm and a length of about 6 cm. For a needle member length of 1.5 - 2.0 cm and a retaining member of about 2

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cm, this gives a security distance of about 2 - 2.5 cm, which is insufficient for a finger length of 5 - 8 cm and a finger diameter of 1.0 - 1.5 cm.

5 Apart from the insufficient protective effect, this art entails that the equipment as such is difficult to operate, since simultaneous operation with both hands is necessary to make the equipment ready for use, which in situations of stress involves a greater risk of incorrect
10 operation and also entails that the shield may erroneously be placed in a position in which the collection tube can be removed without the shield being locked, which increases the risk of accidental contact.

15 The object of the invention is therefore to provide liquid withdrawal equipment for safe and simple withdrawal of liquid samples, in which the risk of accidental contact with the needle points and consequent risk of infection is ob-
20 viated.

20 It has been found according to the invention that this object can be achieved by liquid withdrawal equipment for withdrawing body fluids comprising a holder adapted to receive collection tubes and consisting of a transverse member with a firmly mounted double needle and one or more
25 axial parts connected with said needle, and a shield movably surrounding the holder, characterized in that the holder is provided with a movable protective member adapted to assume a position in which the points of the
30 double needle are protected after retraction of the holder following completed blood withdrawal. Thus, the principle of the invention is based upon the possibility of converting the axial movement of the protective shield with respect to the holder to an inclined or transverse
35 movement of the protective members, which are provided on the holder and are caused, during this movement, to

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protect against contact with the points of the double needle.

5 Liquid withdrawal equipment comprising at least one movable protective member with the characteristic features according to the invention can be provided in several different ways according to the invention.

10 According to the invention, the movement of the protective member or members to protect against contact with the needle points is expediently established by providing and placing at least one first cam means on the inner side of the shield so that the relative movement between the holder and the shield can change the direction of movement of
15 the protective member or members from e.g. a direction in parallel with the axis of the holder to an inclined or transverse movement.

20 According to the invention, a special embodiment is therefore characterized in that at least one movable protective member is adapted to cooperate with a first cam means provided or arranged on the inner side of the shield.

25 According to the invention, the inclined or transverse movement of the protective member or members can also be established in that the protective member or members are provided on or secured to the holder in an arbitrary suitable manner e.g. as a molded tiltable or hinged part of the axial parts of the holder.

30 Special advantages can be obtained according to the invention by securing the protective member either directly to the holder or to one of the non-movable axial parts of the holder in a hinge-like manner so that the protective member
35 can perform a movement in an axial plane, i.e. follow a direction running in a plane through the longitudinal

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axis.

According to a preferred embodiment, the invention is therefore further characterized in that the protective member is so hinged to the rest of the holder as to be movable in an axial plane with respect to the holder.

According to the invention, the "axial parts" of the holder are taken to be parts extending in parallel with the axis of the double needle, e.g. fixed guide rails or supports to retain the movable protective parts.

In preferred embodiments, the axial part may moreover be provided with grips to displace the holder and be equipped with a device for cooperation with the shield.

According to the invention, it has been found particularly advantageous to arrange the equipment such that the holder can easily and neatly be used locked in predetermined positions with respect to the shield by single-handed operation. It is primarily the position of use, in which the front point of the double needle is advanced and ready to be inserted into a vein or similar liquid-containing part of the body.

Locking of the container in the position of use is accomplished according to the invention by adapting the axial parts of the holder to cooperate with a cam means provided on the inner side of the shield, the invention being further characterized in that one of the axial parts, the protective member, of the holder is adapted to cooperate with a second cam means provided or arranged on the inner side of the shield to lock the holder in a position of use during liquid withdrawal.

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In addition to the position of use, the predetermined positions include the final position in which both points of the double needle are protected.

5 Locking of the holder in the final position is characterized according to the invention in that one of the axial and tiltable parts of the holder is formed with a grip to cooperate with a slot, which is formed in the shield and has catches to lock the holder in a permanent final position after completed liquid withdrawal.

10 The predetermined positions finally include the initial position in which both points of the double needle are protected during storage of the equipment.

15 Retaining of the holder in the initial position is accomplished according to the invention by providing the slot with catches. In a preferred embodiment, the invention is therefore characterized in that the slot with the catches is additionally adapted to clampingly engage the grip portion of the holder to retain the holder in the initial position during storage of the equipment.

20 It has moreover been found according to the invention that particularly advantageous protection of the front point of the double needle can be obtained by forming the closed end of the shield with a two-part channel, in which the needle point can be received and guided, without its sharpness being diminished by contact with e.g. the wrapping material for sterile storage of the equipment.

25 The invention is therefore further characterized in that the shield is formed with a closed end provided with a two-part channel to receive and guide one end of the double needle.

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Simple access for receiving collection tubes is an important prerequisite for safe and simple withdrawal of the liquid sample. This facility is provided for according to the invention by forming the cut-out in the open end of the shield as well as establishing a relatively short distance to the axial parts of the holder which receive the collection tube.

The invention is therefore further characterized in that the shield is provided with an open end formed with a cut-out.

"Fluid" in the sense of the invention include e.g. body fluids, such as blood and lymph, as well as other body fluids from organs or liquid-containing cavities in the body.

"Double needle" in the sense of the invention is taken to mean a single or two-part needle device comprising at least a hollow needle through which fluid can flow, and whose oppositely directed needle points are adapted to pierce a vein or similar fluid-containing parts of the body and to pierce at least a membrane or similar cover, which optionally covers a collection tube, such as e.g. an evacuated collection tube, in hermetic and sterile relationship.

Depending upon the embodiment, the needle members may in general have arbitrary shapes, such as curved, circular and/or spiral or rectilinear. Rectilinear needle members are preferred in particular.

The needle members may moreover be equipped with or be incorporated in fluid blocking devices which can block fluid flow when e.g. a collection tube has not yet been received in the holder and the rear point of the needle has not pe-

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netrated the membrane cover of the vacuum collection tube.

5 In a particularly simple embodiment the blocking devices consist of a rubber hose closed at one end, which can be penetrated by the rear needle point when this penetrates the membrane cover of the collection tube during the reception of said tube in the holder.

10 The movement of the collection tube during the receiving operation causes the rubber hose to be compressed and thereby to build up tension, which is later relieved upon removal of the collection tube, so that the closed end of the rubber hose is again caused to block flow of fluid sample.

15 A double needle in the sense of the invention may moreover be equipped with attachment devices by which it can be attached to the holder, e.g. by means of threads, glueing or moulding. Suitable commercially available needles, e.g. 20 Neotube from Nipto, may be used as double needles in the sense of the invention.

"Collection tube" in the sense of the invention is taken to be a sample container which can be evacuated and maintain a vacuum e.g. by means of a membrane or the like 25 which can be pierced by the needle point. The container may be made of any suitable material, e.g. glass or polymer, of varying dimensions, e.g. a diameter of 1.6 cm and a length of 10 - 12 cm. Typical standard vacuum collection 30 tubes are e.g. Vacutainer® from Becton Dickinson and Venject® from Terumo.

Another object of the invention is to provide liquid sample withdrawal equipment according to the invention 35 which is made by injection moulding.

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It has been found that equipment according to the invention can be expediently produced in a simple and inexpensive manner by injection moulding, the shield being moulded in a single operation in two parts in which the holder with axial parts and double needles can simply be inserted during the assembling operation, the two parts being folded around said members prior to being locked, thereby forming the finished liquid withdrawal equipment ready for wrapping and sterilization e.g. by gamma-irradiation, gas or vapour sterilization.

The invention is therefore characterized in that the shield is injection moulded in two parts which are folded around the inserted holder with axial parts and double needle during the assembling operation, following which the shield is locked.

Any suitable injection moulding material, e.g. a transparent plastics material such as polypropylene or polycarbonate, may be used as a material for making the shield in the injection moulding.

The liquid withdrawal equipment can easily be operated by moving the holder with the double needle by the thumb forwardly to the position of use and directly inserting the needle in e.g. the patients vein merely by one hand. After insertion in this, samples are retained by fluid blocking devices around the rear needle point. Only when a vacuum collection tube is received does the rear needle point penetrate the covering membrane of the collection tube, and the sample can flow into the collection tube. After withdrawal of the sample, the collection tube can easily be replaced by a new one, with the fluid blocking device around the rear needle point again covering said point. Then the container can be returned to its rear permanent final position by slight movement of the thumb

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while the needle is pulled out of the vein; in the final position the double needle is surrounded at both ends by the shield and is covered by the protective member. The equipment can then be put aside and be disposed of without
5 any risk of accidental contact with the points of the double needle during subsequent handling operations.

The invention will be explained more fully by the following description of preferred embodiments with reference to
10 the drawings, in which

figs. 1A - C show a holder with a double needle and axial parts,

15 fig. 2 is a longitudinal section through the protective shield,

fig. 3 shows the protective shield with a slot and a catch as well as an advanced front needle,

20

fig. 4 shows the liquid withdrawal equipment comprising the holder with axial parts and a shield,

fig. 5 shows the liquid withdrawal equipment in the position of use comprising a holder with axial parts and a
25 shield as well as a received collection tube,

figs. 6a - e show cross-sections VIa - e of the liquid withdrawal equipment of fig. 5,

30

fig. 7 shows the liquid withdrawal equipment in the final position with the protective member covering the rear end of the double needle, and

35 fig. 8 shows the developed shield after injection moulding.

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Figs. 1A, B and C as well as figs. 2 and 3 show the holder 10 and the shield 20, respectively, adapted to cooperate slidably with respect to each other between the initial position, fig. 4, the position of use, fig. 5, and the final position, fig. 7, respectively.

Fig. 1A shows the holder 10 formed with a transverse member 11, which firmly mounts a double needle 121, 122 with a front needle point 121 and a rear needle point 122 without fluid blocking devices (123, fig. 4) as well as one or more axial parts 131, 132, 133 which are connected therewith and consist of a firm part 131A, on which a tiltable part 132A with a grip 132B is attached, said tiltable part being movable in an axial plane in the directions indicated by the double arrow in fig. 1B.

The extent of the movement is determined by a collection tube optionally received in the holder.

The holder 10 is moreover formed with a movable protective member 133, which is so hinged to the transverse member 11 as to be movable with respect to the holder in an axial plane inwardly towards and to cover the point of the rear part 122 of the double needle.

In an alternative embodiment the protective member 133 may be hinged to another firm part 131B, fig. 1C, of the transverse member 11.

Fig. 2 shows the shield 20, which has a first cam means 21 provided or arranged on the inner side, said cam means 21 being adapted to cooperate with the protective member 133, as well as a second cam means 22 adapted to cooperate with the movable part 132A with the grip 132B and the slot 25 in the shield 20 in fig. 3 to lock the holder 10 in a position of use, fig. 5, during liquid withdrawal.

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The shield 20 is moreover provided with a closed end 23, which is formed with a two-part channel 231, 232 to receive and guide the front end 121, fig. 4, of the double needle. The channel 231, 232 is moreover so arranged that
5 the cutting portion of the needle point 121 is untouched by the needle part 231, while the channel part 232 supports and guides the front end 121 of the double needle, fig. 4.

10 The shield 20 is finally provided with an open end 26, fig. 2, formed with cut-outs, which make it a simple operation to mount collection tubes.

Fig. 3 shows the equipment in the position of use, in
15 which the front point 121 of the needle is advanced, and shows catches 24 and a slot 24 to cooperate with the movable part 132A with the grip 132B.

Fig. 4 shows a longitudinal section of the liquid withdrawal equipment in its initial position. In this position, which is maintained by cooperation between the grip
20 132B and the catches 24, the cutting portion of the point on the front end 121 of the double needle is protected against contact and can thus retain its sharpness until
25 use. The figure also shows fluid blocking devices 123 in the form of a closed rubber hose.

The liquid withdrawal equipment is preferably supplied in this initial position and is also wrapped in a sterile
30 package (not shown) according to known methods.

Fig. 5 shows a longitudinal section of a preferred embodiment of the liquid withdrawal equipment in the position of use after reception of a collection tube 30 with a plug
35 31, pierced by the rear part 122 of the double needle. The rubber hose 123 is shown compressed in this position and

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partially fills the space between the transverse member 11 and the plug 31.

5 The position is moreover maintained by cooperation between the movable part 132A with the grip 132B and the second cam means 22.

10 Fig. 5 is moreover provided with references to the cross-sections IVa - e, as shown in figs. 6a - e, to be seen from the end in which the collection tube is received.

To lock the holder 10 in a permanent final position, fig. 7, after completed fluid withdrawal, the shield 20 is formed with catches 24 and a slot 25, fig. 3, which coope-
15 rates with the movable part 132A and the grip 132B of the holder such that the holder 10 cannot be advanced again.

Fig. 7 moreover shows the final position of the protective member 133, which, in cooperation with the cam means 21,
20 has been caused to cover the rear part 122 of the double needle. Part of the rubber hose in its extracted position is likewise shown.

Fig. 8 shows a cross-section through the two integral, in-
25 jection moulded parts 20A and 20B.

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P a t e n t C l a i m s :

1. Liquid withdrawal equipment for withdrawing preferably
5 body fluids, such as blood and lymph, comprising a holder
(10) adapted to receive collection tubes and consisting of
a transverse member (11) with a firmly mounted double
needle (121, 122) and one or more axial parts (131, 132,
10 133) connected with said needle, and a shield (20) movably
surrounding the holder, c h a r a c t e r i z e d in that
the holder (10) is provided with at least one movable pro-
tective member (133) adapted to assume a position in which
the points (121, 122) of the double needle are protected
after retraction of the holder following completed blood
15 withdrawal.
2. Liquid withdrawal equipment according to claim 1,
c h a r a c t e r i z e d in that at least one of the
protective members (133) is adapted to cooperate with a
20 first cam means (21) provided or arranged on the inner
side of the shield (20).
3. Liquid withdrawal equipment according to claim 1 or 2,
c h a r a c t e r i z e d in that the protective member
25 (133) is so hinged to the rest of the holder as to be mov-
able in an axial plane with respect to the holder.
4. Liquid withdrawal equipment according to any of the
preceding claims, c h a r a c t e r i z e d in that one
30 of the axial parts (132A) of the holder is adapted to co-
operate with a second cam means (22) provided or arranged
on the inner side of the shield (20) to lock the holder in
a position of use during blood withdrawal.
- 35 5. Liquid withdrawal equipment according to any of the
preceding claims, c h a r a c t e r i z e d in that one

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of the axial parts (132A) of the holder is additionally provided with a grip (132B) to cooperate with a slot (25) which is formed in the shield and has catches (24) to lock the holder (10) in a permanent final position after completed blood withdrawal.

6. Liquid withdrawal equipment according to any of the preceding claims, characterized in that the slot (25) with the catches (24) is additionally adapted to clampingly engage the grip portion of the holder to retain the holder in an initial position during storage of the equipment.

7. Liquid withdrawal equipment according to any of the preceding claims, characterized in that the shield (20) is formed with a closed end (23) provided with a two-part channel (131, 132) to receive and guide one end of the double needle.

8. Liquid withdrawal equipment according to any of the preceding claims, characterized in that the shield is provided with an open end (26) formed with cut-outs.

9. Liquid withdrawal equipment according to any of the preceding claims, characterized in that the shield is injection moulded in two parts, which are folded around the inserted holder with axial parts and double needle during the assembling operation, following which the shield is locked.

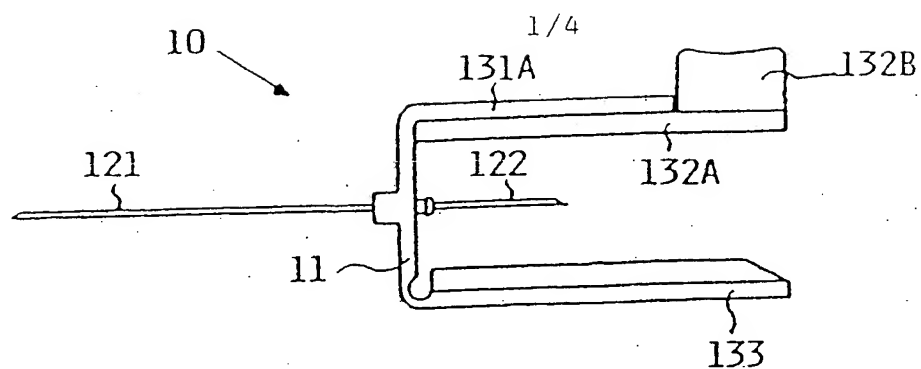


FIG. 1A

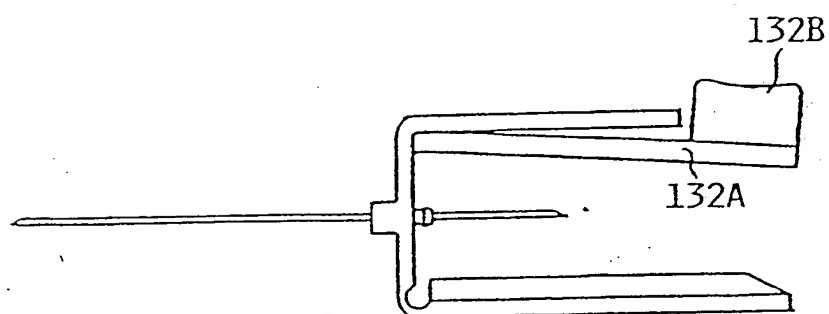


FIG. 1B

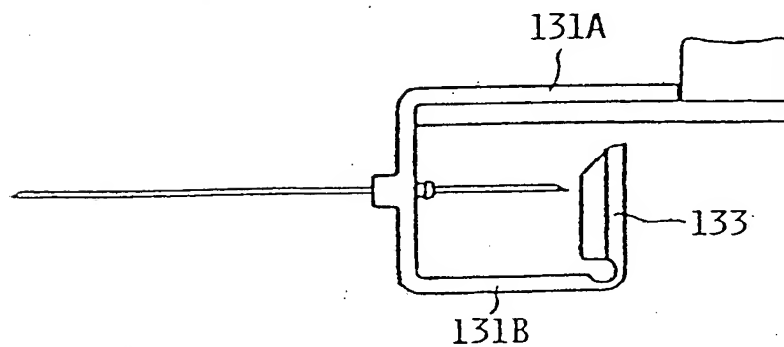
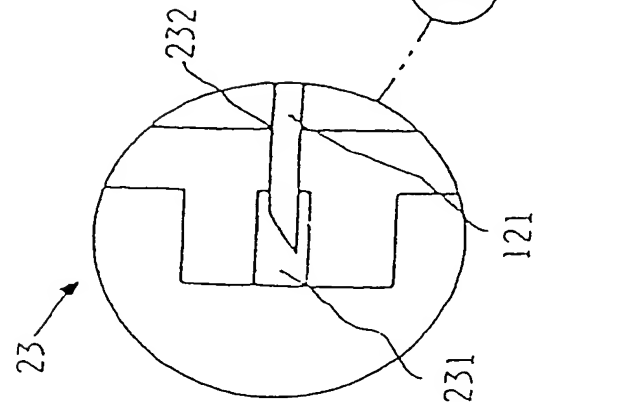
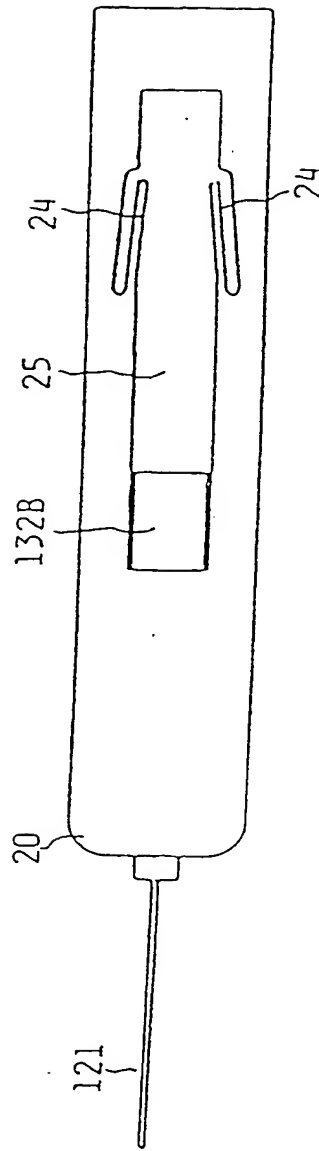
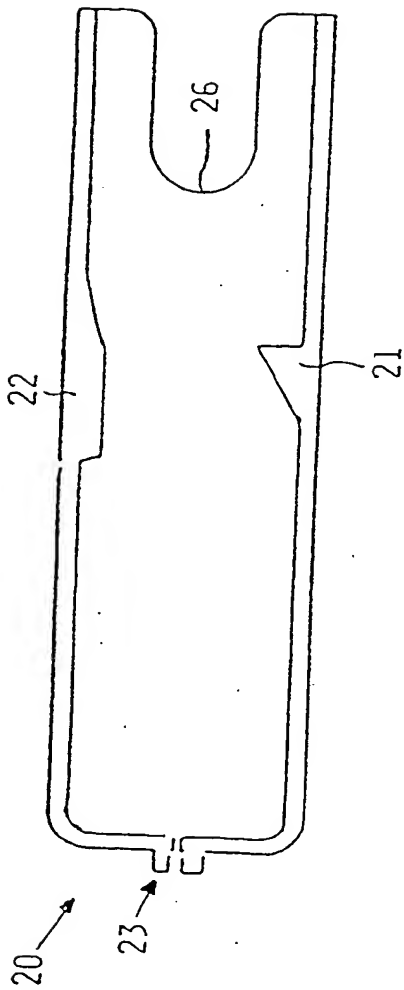


FIG. 1C



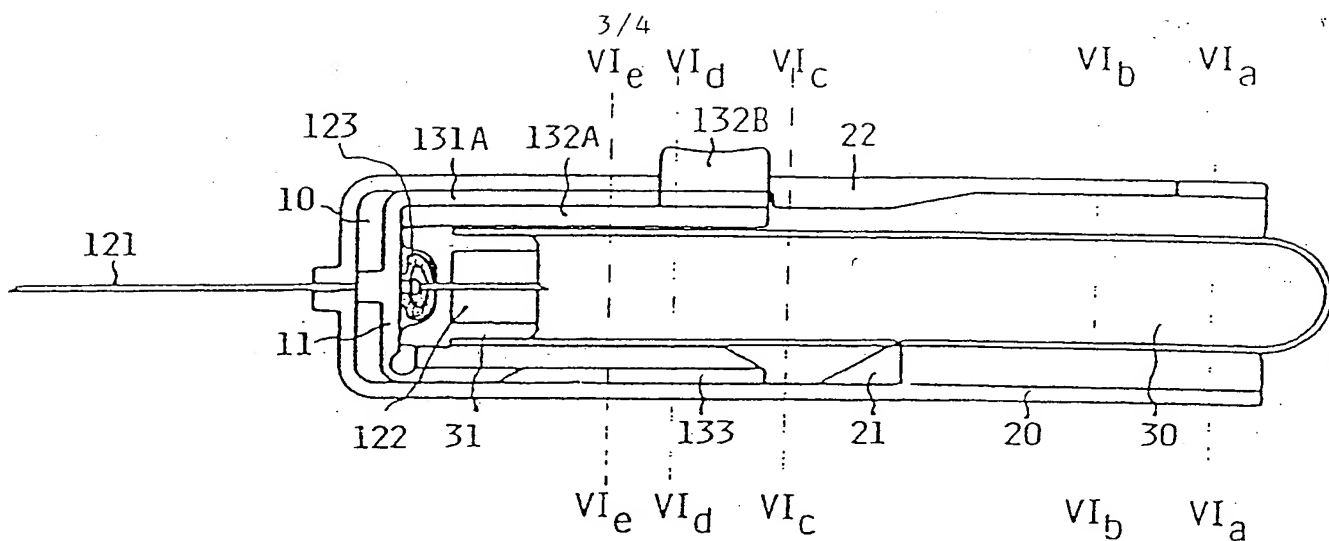


FIG. 5

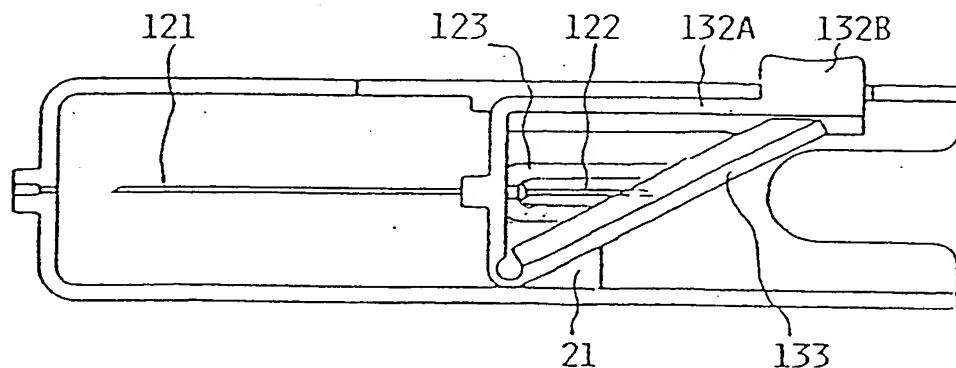


FIG. 7

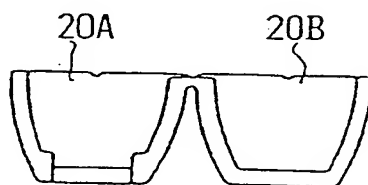


FIG. 8

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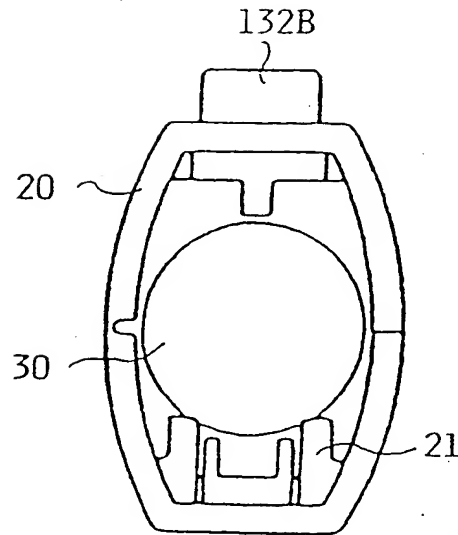


FIG. 6A

FIG. 6B

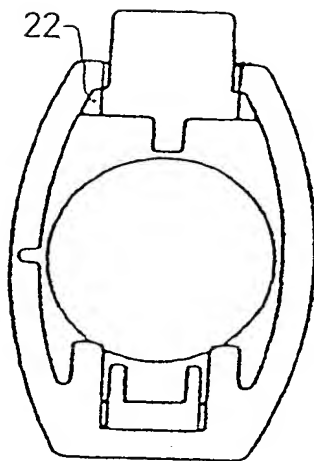


FIG. 6C

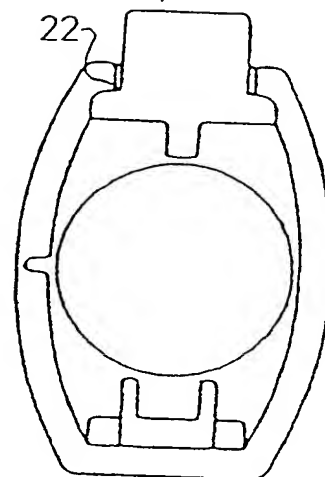


FIG. 6D

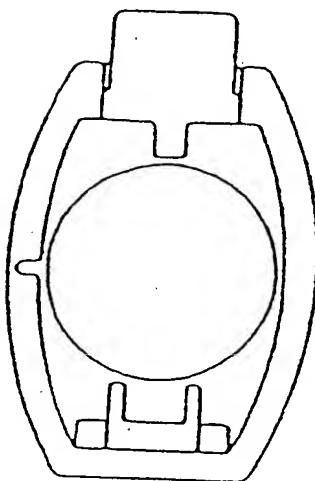
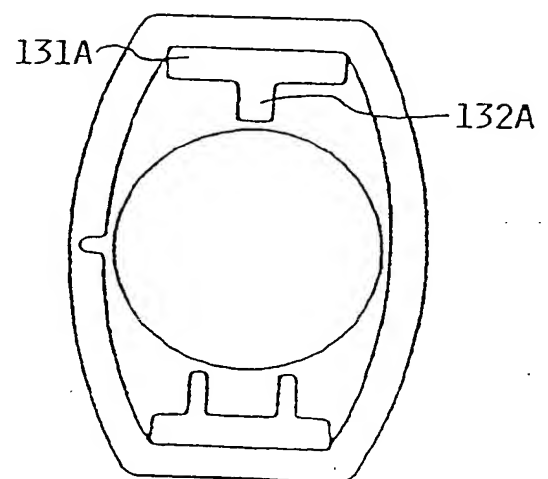


FIG. 6E



INTERNATIONAL SEARCH REPORT

International Application No. PCT/DK 89/00215

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC IPC4: A 61 B 5/14, A 61 M 5/32		
II. FIELDS SEARCHED		
Minimum Documentation Searched *		
Classification System:	Classification Symbols	
IPC4	A 61 B, A 61 M	
Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched *		
SE,DK,FI,NO classes as above		
III. DOCUMENTS CONSIDERED TO BE RELEVANT *		
Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
P,X	US, A, 4774964 (J.M. BONALDO) 4 October 1988, see figures 1,2, details 24,32,38 --	1
A	US, A, 4643199 (B.P. JENNINGS, JR. ET AL) 17 February 1987, --	1
A	US, A, 4752290 (J.J. SCHRAMM) 21 June 1988, see figures 1-3 --	1,2,4
A	US, A, 4592744 (J.C. JAGGER ET AL) 3 June 1986, see figures 4-6 --	1
A	US, A, 4758231 (T. HABER ET AL) 19 July 1988, see figures 1-2 --	1,2,4
<p>* Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search 15th December 1989	Date of Mailing of this International Search Report 1989 -12- 27	
International Searching Authority SWEDISH PATENT OFFICE	Signature of Authorized Officer Anders Holmberg <i>Anders Holmberg</i>	

Form PCT/ISA/210 (second sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. PCT/DK 89/00215

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4774964	04/10/88	NONE	
US-A- 4643199	17/02/87	NONE	
US-A- 4752290	21/06/88	US-A- 4826491	02/05/89
US-A- 4592744	03/06/86	NONE	
US-A- 4758231	19/07/88	EP-A- 0288879	02/11/88
		US-A- 4790827	13/12/88
		JP-A- 63317160	26/12/88
WO-A1- 89/04141	18/05/89	AU-D- 27167/88	01/06/89

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
P,A	WO, A1, 89/04141 (WEIBEL S. E.) 18 May 1989, see the whole document -----	1

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